

## RUGBY LABORATORIES PAYS \$7.5 MIL TO SETTLE GOVERNMENT V-A PRICING FRAUD ALLEGATIONS; FORMER EMPLOYEE WHO BROUGHT QUI TAM SUIT RECEIVES \$1.1 MIL

Rugby Laboratories is paying \$7.5 mil. to settle a suit alleging that the generic drug distributor overcharged the Department of Veterans Affairs, the Justice Department announced Oct. 31.

The Rugby case concerns a five-year, \$40 mil. contract that Rugby won in 1991 to provide generic pharmaceuticals to V-A hospitals. The initial solicitation by Rugby in 1988 guaranteed that "resultant contracts and orders constitute the lowest overall cost alternative to meet the minimum needs of the government," according to the complaint in the case.

The suit charges that: "Rugby has sold to its other customers at lower prices than the price offered to the U.S."; Rugby "has offered rebates to chain drug stores, such as Thrift, Oseco and Say-on, for large quantity purchases without offering the same rebates to the U.S."; and "Rugby has sold products to purchasers other than the U.S. and offered delayed payment and other considerations not offered to the U.S."

Pursuant to 31 U.S.C. 3729, liability for fraud against the U.S. government consists of a civil penalty of \$5,000 to \$10,000 plus triple damages. The damages in the Rugby case have been defined as "the amount that [the U.S.] has paid in excess of the best price offered to other like purchasers."

The case has been dismissed with prejudice, and the settlement agreement notes that "Rugby expressly denies the allegations set out above and denies that the U.S. is entitled to a recovery and further asserts that it acted properly and in accordance with all applicable statutes and regulations."

Hoechst Marion Roussel, which acquired Rugby as part of the Hoechst-Roussel/Marion Merrell Dow merger, states that it is satisfied with the settlement, and that the company looks forward to continued provider service for the government. Rugby, which was acquired by Marion in October 1993, posted sales of \$296 mil. in 1994.

Former Rugby employee Eileen Doran filed the initial whistle-blower complaint in Chicago federal court on Nov. 9, 1994 as a *qui tam* plaintiff in the name of the U.S.

"Under the *qui tam* provisions of the False Claims Act," the Justice Department states, "a private party can file an action on behalf of the United States and receive a portion of the settlement if the government takes over the case and prosecutes it successfully." Doran receives \$1.05 mil. of the final settlement, with the remaining \$6.45 mil. going to the U.S.

At a recent Regulatory Affairs Professional Society annual meeting, attorney Ronald Clark of the D.C. firm Arent, Fox predicted that "we are entering into an era where we are likely to have a large number of *qui tam*" lawsuits brought by whistle-blowers.

Clark referred in his speech to the \$161 mil. settlement paid by Caremark to settle allegations that the company violated the Medicare and Medicaid anti-kickback statute. The attorney recommended that drug companies adopt compliance programs to protect against costly fraud complaints ("The Pink Sheet" Sept. 25, T&G-13).

In 1991, Hoechst-Roussel was praised by a California pharmacists' group for its pricing policy, which acknowledged only two basic customer types: government accounts, which received an added price break, and non-government accounts. Hoechst Marion Roussel indicates that Rugby's future pricing policy will be dictated by both Hoechst-Roussel and MMD policies.

DD 0102

## **APhA/NWDA "CONCEPT PHARMACY" TO USE CASE STUDIES TO BUILD Rx CARE MARKET; APhA's GANS WARNS OTHER PROFESSIONS WILL FILL NICHE IF PHARMACY DOES NOT**

Data gleaned from 30 telephone interviews and 16 site visits with pharmaceutical care innovators will generate much of the material for the "Concept Pharmacy" exhibit, scheduled to debut at the American Pharmaceutical Association annual meeting in March, project leaders reported at the National Wholesale Druggists Association annual conference Oct. 30 in Palm Desert, Calif.

Innovators profiled in the Concept Pharmacy project are split among community, ambulatory care, hospital, mail-order, consulting and novel practice settings. Sites visited include CVS/MedOutcomes disease management pharmacies and disease management provider Brema Pharmacy in Richmond, Va.; hospital-based Kaiser Permanente oral anticoagulation clinic in San Francisco; and Stadtlander's specialty mail-service location in Pittsburgh.

**Through live presentations, mock-ups, interactive computer kiosks, displays and videos, the Concept Pharmacy exhibit is designed to spread the news about pharmaceutical care by depicting specific pharmaceutical care practices that innovator pharmacies have developed.**

CVS and MedOutcomes have an arrangement for twice-weekly disease management clinics for diabetes, asthma, hypertension and hypercholesterolemia. Brema Pharmacy counsels patients on diabetes, hypertension, cholesterol and urological disorders. Brema's disease management patients are seen by appointment; most patients are referred by physicians.

The Kaiser clinic profiled in Concept Pharmacy tracks patients' oral anticoagulation therapy beginning in the inpatient setting and continuing after discharge. The program is funded by an internal Kaiser grant and has served 450 patients so far. Stadtlander's mail-order pharmacy in Pittsburgh specializes in HIV, kidney transplant and oncology care, providing free 24-hour pharmaceutical and reimbursement counseling for patients in addition to processing 3,800 scripts per day.

Concept Pharmacy also has developed an annotated bibliography listing 104 published studies dealing with economic issues in pharmaceutical care. The bibliography will be made available in March. The board of directors for the project includes pharmacists, manufacturers and wholesalers. The board is chaired by FoxMeyer CareStream (previously HealthConnect) President Bob Davis.

➤ Coopers & Lybrand has been retained as manager for the Concept Pharmacy project. Goodnight/Hermann is the creative designer. NWDA and APhA have set a \$1 mil. fundraising goal for the first phase of the project, which comprises the exhibit and take-home materials for that site. To date, \$540,000 has been raised.

Concept Pharmacy is to be a non-proprietary, market-building project, NWDA VP-Marketing & Communications Bruce Kneeland said at an NWDA trade press luncheon Oct. 31. The initial intent is to create awareness among pharmacists and wholesalers of the possibilities associated with pharmaceutical care.

For pharmacists, the practice models compiled for the Concept Pharmacy project represent enhanced professional satisfaction and potential new revenue sources. At the NWDA meeting Oct. 30, APhA President John Gans warned that if pharmacists do not take the initiative in helping to address prescription drug misuse, other health professionals will fill the public health need. "Someone is going to address" the problem of drug misuse, Gans said, "and I believe the nurses have already started. The major issue here is caregiving, so if pharmacy doesn't address it, if we don't get after it, then we will lose tremendous opportunities."

For wholesalers looking to expand beyond their traditional distribution role, Concept Pharmacy encourages development of information systems and services to help pharmacists deliver pharmaceutical care. "It is important that we assist our customers in building a support system that will enable the patient to gain full value from their drug therapy and minimize the down-side risk," outgoing NWDA Chairman Mel Whitmire said Oct. 29.

The National Association of Retail Druggists and the National Association of Chain Drug Stores have not joined in the Concept Pharmacy effort. NARD has been promoting its National Institute for Pharmacist Care Outcomes, stressing the semantic distinction between "pharmacist" and "pharmaceutical" care. NWDA President Ron Streck wrote to NARD Exec VP Charles West last month inviting collaboration, and talks could begin soon.

DD 0103